

**REMARKS**

Applicants appreciate the Examiner's thorough examination of the subject application and request reconsideration of the subject application based on the foregoing amendments and the following remarks.

Claims 1-44 are pending in the subject application.

Claims 1-44 stand rejected under 35 U.S.C. §101, 35 U.S.C. §102, 35 U.S.C. §103, and/ or 35 U.S.C. §112, first paragraph. Claims 11 and 12 were objected to as depending in improper multiple dependent form.

Claim 11 was amended to address the Examiner's objection to the improper multiple dependent claim. As claim 12 depends only from claim 11, Applicants do not believe that the within objection need be addressed further as to claim 12.

The amendments to the claims are supported by the originally filed disclosure.

**35 U.S.C. §101 & 35 U.S.C. §112, FIRST PARAGRAPH REJECTIONS**

Claims 8, 9, 35, 36, 43 and 44 stand rejected under 35 U.S.C. §101 on the grounds that the claimed invention is not supported by either a non-coplanar arrangement of three fiducial markers asserted utility or a well established utility as provided on page 2 of the above-referenced Office Action. It is further asserted that a claimed element where three fiducial object are in a non-coplanar arrangement is not possible and that any three points in space must lie in a same plane.

It also is asserted that since the claimed invention is not supported by either a non-coplanar arrangement of three fiducial markers as set forth in the §101 rejection, one skilled in the art clearly

would not know how to use the claimed invention.

Applicants respectfully traverse both grounds for rejection as discussed below.

It appears that the within rejection is based on two assumptions (1) the claimed element where three fiducial object are in a non-coplanar arrangement is not possible as any three points in space must lie in the same plane and (2) that the subject application does not support the non-coplanar arrangement. Applicants respectfully disagree with these two apparent assumptions.

Claim 8, which depends from claim 1, includes the further limitation that the fiducial object comprises three N-shaped fiducial motifs and that the three N-shaped fiducial motifs are non-coplanar. Referring now to figures 2a,b of the subject application as well as the discussion at pages 10-11 thereof, there is shown a module including three N shaped fiducial motifs that are arranged so as to form a U-shaped module where one of the fiducial motifs forms the base and the other two fiducial motifs the sides of the U shaped module. It is further indicated that the fiducial motifs are opaque to the image radiation. The dimensioning and coordinate system for each fiducial motif is shown in Fig 3A. Referring now also to Fig. 3B and the discussion on pages 11-14 the process for determining points in space using the three N-shaped fiducials in the arrangement shown in Figs. 2A,B.

Coplanar is generally described for mathematical purposes as lying or being situated in the same plane. It is clear that the three N-shaped fiducial motifs shown in Figs. 2A,B s are not arranged so that they all lie in the same plane. As such, it is appropriate to describe such an arrangement of the three N shaped fiducial motifs as being non-coplanar. Thus, the subject application does provide an enabling disclosure of three N-shaped fiducial motifs that are not co-

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planar or thus non-coplanar that would enable one skilled in the art to use the claimed invention.

It should be recognized that it is within the skill of those knowledgeable in the art to develop other shaped fiducial motifs as well as the techniques by which the points can be arrived using the teachings of the subject application.

Accordingly, claims 8, 9, 35, 36, 43 and 44 satisfy the requirements of 35 U.S.C. §101 and 35 U.S.C. 112, first paragraph and, therefore, these claims are allowable and the specification is considered acceptable.

#### 35 U.S.C. §102 REJECTIONS

The Examiner rejected claims 1-10, 13-23, 28, 30-35 and 37-44 under 35 USC 102(b) as being anticipated by Kalfas et al. [USP 5,776,064; "Kalfas"]. Applicants respectfully traverse as discussed below.

Applicants claim, claim 1, an imaging system for invasive therapy of a patient, where the system includes an imaging apparatus that can provide a cross-sectional image of a patient and a medical instrument that includes a fiducial object that can be simultaneously imaged in the same image as a targeted site of the patient. As indicated previously by Applicants, the claims once read in light of the specification of the present invention would apprise one skilled in the art as to the scope of the claimed invention. As also indicated by Applicants, the independent claims were amended in view of the Examiner's suggestion at that time to expressly indicate in the claims that the medical instrument and the target site are being imaged at the same time. In other words, the image data being acquired includes the fiducial object included with the medical

instrument *and* the targeted tissues, etc. of the patient.

As noted previously by Applicants, this limitation, however, *shall not* be construed as meaning or suggesting that all elements of the area being imaged are acquired in a manner different from that done in accordance with the imaging process. For example, and as is known by those skilled in the art, NMR/ MR imaging is accomplished by imaging or scanning slices of the area being imaged and then reconstructing these slices to produce a complete image. Using this example, it should be understood that the express limitation being added to the claims does not mean that the NMR/MR imaging process is performed differently (for example, the limitation *does not* mean or suggest that all slices are acquired at the same time).

As indicated in the subject application (e.g., see page 4, thereof) such a system provides a mechanism by which the three-dimensional position and orientation of a medical instrument (effector) such as a needle, probe, etc. relative to a subject using one or more cross sectional images of the subject can be determined so as to enable effector placement without use of patient immobilization or separate fiducial implantation. In addition, by placement of a fiducial object separate from a patient but in association with a medical instrument, a single cross-sectional image can be taken via an imaging device such as Computed Tomography, Magnetic Resonance Imaging or ultrasound, and that single image can be employed to directly manipulate and orient the medical instrument during the course of a surgical procedure.

In contrast to the present invention, Kalfas does not describe a system where the medical instrument that includes a fiducial object that can be simultaneously imaged in the same image as a targeted site of the patient. The system described in Kalfas includes a frame 12 that is mounted in

fixed relation to the patient such that it is precisely positioned within the subject or subject support coordinate system (see col. 2, lines 38-45 thereof). It is further described that the frame 12 supports a plurality of receivers 14 such a microphones, radio frequency receivers and the like mounted at fixed, known locations thereon. It is further provided that a securing means 16 is provided to securely position a portion of the subject under consideration (See col. 2, lines 50-58 thereof).

This system of Kalfas further includes a wand 40 having a tip portion or proximal end 44 upon which a pair of emitters 48, 50 are mounted, where the first emitter is a fixed distance from the tip portion and the second emitter is a fixed distance from the first emitter. (See col. 3, lines 19-31 thereof). It is clear from the discussion that follows in cols 3-8 of Kalfas that the position of the wand is determined by use of the signals from the emitters 48, 50 and the receivers 14 fixed to the frame 12.

The discussion that follows also describes the use of fiducials affixed to the body or bones of the patient as a mechanism for registering or aligning the patient space with the image space stored in memory (see col. 7, line 32 - col. 8, line 17 thereof). It also is indicated that such registering or aligning of the patient space with the image space is required before the wand a tool guide can be used to locate a proper coordinate and trajectory for a surgical toll such as a drill.

It also is clear from the discussion in Col. 8, that what is being illustrated in figure 6A as well as figures 6B-C in Kalfas is a preferred coordinate transform between the coordinate system of the data and the patient.

In sum, Kalfas does not disclose the system of claim 1, rather it describes another system using other techniques for determining coordinates which may involve the use of fiducials that are

affixed to the patient so as to align coordinate data acquired using the receivers and emitters to the patient space. This technique and system is completely different from that of the presently claimed invention. In fact, a particular advantage of the system and methodology of the present invention is that one does not have to perform the additional steps of affixing fiducials to a body and acquiring data so as to align the image and patient spaces as is taught and disclosed in Kalfas.

Moreover, it is clear that whatever Kalfas discloses, Kalfas does not and cannot disclose a system or a technique embodied in such a system where an imaging apparatus that can provide a cross-sectional image of a patient and a medical instrument that includes a fiducial object that can be simultaneously imaged in the same image as a targeted site of the patient. As it is clear that in Kalfas the fiducial object(s) are mounted on the patient and not the medical instrument or the tool.

It is respectfully submitted that the foregoing reasons distinguishing claim 1 at least apply to distinguish each of claims 2-10, 13-23, 28, 30-35 and 37-44 from Kalfas.

As provided in MPEP-2131, a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Or stated another way, "The identical invention must be shown in as complete detail as is contained in the ... claims. *Richardson v Suzuki Motor Co.*, 868 F.2d 1226, 9 USPQ 2d. 1913, 1920 (Fed. Cir. 1989). Although identify of terminology is not required, the elements must be arranged as required by the claim. *In re Bond*, 15 USPQ2d 1566 (Fed. Cir. 1990).

It is respectfully submitted that for the foregoing reasons, claims 1-10, 13-23, 28, 30-35 and 37-44 are patentable over the cited reference and satisfy the requirements of 35 U.S.C. §102(b). As

such, these claims, including the claims dependent therefrom are allowable.

### 35 U.S.C. 103 REJECTIONS

Claims 24-27 and 29 stand rejected under 35 U.S.C. 103 as being unpatentable over Kalfas et al. [USP 5,776,064; "Kalfas"] as applied to claim 16 above in view of Gillies et al. [USP 6,272,370; "Gillies"]. Applicants respectfully traverse as discussed below. Applicants would note that within rejection is being addressed on the assumption that the principal reference is Kalfas and not Gillies as had been indicated in the Office Action, as the remarks that follow as well as the language "as applied to claim 16 above" would only be proper if Kalfas was the principal reference.

Each of claims 24-25 and 27 depend from claim 16, which claim as indicated above is not described in Kalfas. More specifically, and with reference to the remarks above regarding claim 1, Kalfas does not disclose a method for guiding invasive therapy in a patient that includes providing a medical instrument including a fiducial object that can be simultaneously imaged in the same image as the targeted site as well as not disclosing obtaining a cross-sectional image that comprises both the target site of the patient and the fiducial object. It also is respectfully submitted that Kalfas also does not disclose, teach nor suggest the methodology of claim 16 as well as not providing any teaching, suggestion nor offer any motivation for modifying the methodology disclosed in Kalfas so as to yield the method of claim 16. As such, it is respectfully submitted that each of claim 25-25 and 27 also are considered to be allowable at least because of their dependency from a base claim that is considered to be allowable.

It also appears that Gillies is being used for the limited purposes of its therapeutic injection

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teachings and thus the combination of the teachings of Kalfas and Gillies also would not yield the inventions of claims 24-25 and 27. As such, it is respectfully submitted that each of claim 24-25 and 27 would be allowable for this further reason.

As provided in MPEP 2143.01, obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. *In re Fine*, 837 F. 2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988); *In re Jones*, 958 F. 2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). As provided above, the references cited, alone or in combination, include no such teaching, suggestion or motivation.

Furthermore, and as provided in MPEP 2143.02, a prior art reference can be combined or modified to reject claims as obvious as long as there is a reasonable expectation of success. *In re Merck & Co., Inc.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Additionally, it also has been held that if the proposed modification or combination would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious. Further, and as provided in MPEP-2143, the teaching or suggestion to make the claimed combination and the reasonable suggestion of success must both be found in the prior art, not in applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). As can be seen from the forgoing discussion regarding the disclosures of the cited references, there is no reasonable expectation of success provided in the reference or the admitted prior art. Also, it is clear from the foregoing discussion that the modification suggested by the



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Examiner would change the principle of operation of the system and method disclosed in Kalfas.

It is respectfully submitted that for the foregoing reasons, claims 24-215 and 27 are patentable over the cited reference(s) and thus satisfy the requirements of 35 U.S.C. §103. As such, these claims are allowable.

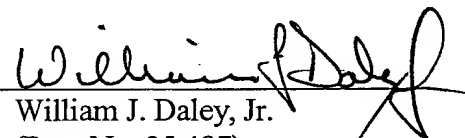
It is respectfully submitted that the subject application is in a condition for allowance. Early and favorable action is requested.

Applicants believe that additional fees are not required for consideration of the within Response. However, if for any reason a fee is required, a fee paid is inadequate or credit is owed for any excess fee paid, the Commissioner is hereby authorized and requested to charge Deposit Account No. 04-1105.

Respectfully submitted,  
Edwards & Angell, LLP

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